

Reply Exhibit 4

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MEDICARE PAYMENTS FOR MEDICAL SUPPLIES

HEARING

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UNITED STATES SENATE
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PREPARED STATEMENT OF JANET REHNQUIST

Good morning, Mr. Chairman and Members of the Subcommittee. I am Janet Rehnquist, Inspector General of the Department of Health and Human Services. I appreciate this opportunity to appear before you today to discuss some of the issues we have encountered with fraud, waste and abuse related to Medicare reimbursement for medical equipment and supplies.

We continue to find that Medicare and its beneficiaries pay too much for medical equipment and supplies. You have specifically asked us to compare the price Medicare pays for certain medical equipment and supplies with that of other payers, including the Department of Veterans Affairs (VA), Medicaid, Federal Employee Health Benefit (FEHB) plans, and retail suppliers. Our price comparison demonstrates that Medicare overpays for some medical equipment and supplies.

The problems that we are discussing today are not new. We have done numerous reviews over the years documenting excessive reimbursement for medical equipment and supplies. The Centers for Medicare & Medicaid Services (CMS), the General Accounting Office (GAO) and Members of Congress such as yourself, Mr. Chairman, have done much to improve Medicare's reimbursement for medical equipment and supplies. Improvements include creating supplier standards, centralizing claims processing into four regional carriers, and reducing oxygen reimbursement by 30 percent. In addition, inherent reasonableness authority and competitive bidding demonstrations have been promising approaches to reduce excessive reimbursement. We believe that even more has to be done, and my testimony today will outline some specific steps to reduce or eliminate problems that continue today.

BACKGROUND

Medicare Part B expenditures for all medical equipment and supplies totaled more than \$6.8 billion in 2000, of which beneficiaries paid more than \$1.3 billion out of their own pockets. Medicare covers certain medical equipment and supplies, which include several categories of items. Durable medical equipment (DME) are items that can withstand repeated use and include oxygen equipment, hospital beds, wheelchairs, and other equipment that physicians prescribe for home use. Medicare Part B also covers certain drugs necessary for the effective use of DME, including albuterol for use with a nebulizer. Prosthetic devices replace all or part of a body organ. Medicare covers enteral and parenteral nutrition therapy under this benefit. Medical supplies include catheter, ostomy, incontinence, and wound care supplies. Medicare also covers braces and artificial limbs.

RECENT OIG WORK

We have conducted numerous studies in recent years, all showing that Medicare pays too much for certain medical equipment and supplies.

Maintenance Payments for Capped Rental Equipment.—In a report we are releasing today entitled *Medicare Maintenance Payments for Capped Rental Equipment*, we reviewed Medicare's maintenance payments that are made under the capped rental payment category. We found that Medicare paid substantially more for maintenance on rented equipment than repairs on purchased equipment. Medicare pays for maintenance even if the supplier does not service the equipment. Furthermore, our additional analysis of supplier documentation found only 9 percent of the capped rental equipment actually received any maintenance and servicing. We estimated that Medicare could save approximately \$100 million per year by eliminating maintenance payments and, instead, pay only for repairs when needed. CMS concurred with our recommendation to eliminate maintenance payments and will seek legislation to eliminate the purchase option under the capped rental category.

Respiratory Assist Devices.—In June 2001, we issued a report entitled *Respiratory Assist Devices With Back-up Rate*. We concluded that the current Medicare payment method used for bi-level respiratory assist devices with back-up rate is inappropriate. Medicare could save \$11.5 million annually if this item were classified as a "capped rental" item rather than an item needing "frequent and substantial service". CMS is currently in the process of making this change.

Prescription Drugs Used with Medical Equipment.—In March 2002, we released a report entitled *Excessive Medicare Reimbursement for Albuterol*. We found that Medicare and its beneficiaries would save \$264 million a year if albuterol were reimbursed at the median VA price and between \$226 million and \$245 million if reimbursed at prices available to suppliers. A separate March 2002 report entitled *Excessive Medicare Reimbursement for Ipratropium Bromide* found that Medicare and its beneficiaries would save \$279 million a year if ipratropium bromide were reim-

bursed at the median VA prices and between \$223 million and \$262 million a year if reimbursed at prices available to suppliers.

Blood Glucose Test Strips.—In a June 2000 report entitled *Blood Glucose Test Strips: Inappropriate Medicare Payments*, OEI-03-98-00230, we found that Medicare allowed \$79 million for blood glucose test strip claims with missing or flawed documentation. Orders for 25 percent of the sampled claims failed to establish beneficiaries' eligibility for the supplies. Another 21 percent of claims had incomplete orders. We found that suppliers submit claims for test strips at irregular intervals, making it difficult to identify overlapping claims, claims without correct supporting documentation, and claims for excessive numbers of test strips. We recommended that CMS take several steps to promote compliance with Medicare guidelines for blood glucose test strips.

We have performed numerous other reviews which consistently found that Medicare pays too much for certain items of medical equipment and supplies because Medicare reimbursement rates are based on charges submitted to the program in 1987. As a result, Medicare payments can bear little resemblance to prices available in the marketplace or to the actual cost of manufacturing and distributing the equipment.

PRICE COMPARISONS FOR 16 MEDICAL EQUIPMENT AND SUPPLY ITEMS

The price comparisons that you requested confirm once again that Medicare pays more than other payers for certain medical equipment and supplies. We compared Medicare payment rates for medical equipment and supplies to the rates of other payers, and provided an estimate of potential savings if the Medicare program were to adopt the rates of these payers.

Our analysis shows that health care consumers, Federal health insurance plans, State Medicaid agencies, and the VA pay less than Medicare for some of the medical equipment and supplies we reviewed. However, this analysis was not designed to follow the same process for rate setting purposes that CMS will need to employ using the inherent reasonableness authority authorized in Section 4316 of the Balanced Budget Act of 1997. In order for CMS to affect a payment reduction for items in our analysis, they would have to conduct a separate inherent reasonableness determination in accordance with procedures set forth in regulations. As discussed later in my testimony, revised standards have to be promulgated before this authority can be utilized.

Also, unlike Medicare, which is a payer of services and not a provider of services, the VA generally obtains medical equipment and supplies by direct acquisition from manufacturers and wholesalers. The prices that the VA pays for medical equipment and supplies provide a rough estimate of the wholesale prices available to large purchasers. These prices do not take into account the Medicare supplier costs associated with getting an item to a Medicare beneficiary.

For our analysis, we compared the median Medicare price for 16 medical equipment and supply items with the median prices from the VA, State Medicaid agencies, fee-for-service FEHB plans, and retail suppliers. Twelve of these items were researched by the Chairman's staff in 1996. The remaining four items had very large total Medicare payments in 2000. The 16 items we reviewed represent more than \$1.7 billion (26 percent) of \$6.8 billion in total allowed charges for medical equipment and supplies in 2000.

The table below provides a description for each of the 16 codes reviewed. The methodology is provided as an appendix to this testimony.

Medicare Code	Description
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4259	Lancets, per box of 100
A4323	Sterile saline irrigation solution, 1000 ml
B4035	Enteral feeding supply kit; pump fed, per day
E0135	Walker, folding (pickup), adjustable or fixed height
E0163	Commode chair, stationary, with fixed arms
E0178	Gel or gel-like pressure pad or cushion, nonpositioning
E0180	Pressure pad, alternating with pump
E0181	Pressure pad, alternating with pump, heavy duty
E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress
E0277	Powered pressure-reducing air mattress
E0570	Nebulizer, with compressor
E0730	TENS (transcutaneous and/or neuromuscular electrical nerve stimulators), four lead, larger area/multiple nerve stimulation

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Medicare Code	Description
E0776	IV pole
K0001	Standard wheelchair
K0011	Standard-weight frame motorized/power wheelchair with programmable control parameters for speed adjustment, tremor dampening, acceleration control and braking

The results of our review are presented in the following table:

SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS

Medicare code	Median Medicare price	Median VA price without markup	Percentage difference between Medicare and VA without markup	Median VA price with 67 percent markup	Percentage difference between Medicare and VA with 67 percent markup	Median Medicaid price	Percentage difference between Medicare and Medicaid	Median retail price	Percentage difference between Medicare and retail	Median FEHP price	Percentage difference between Medicare and FEHP
A4253	\$38.32	\$19.50	49.11	\$32.57	15.01	\$35.81	6.55	\$42.42	-10.70	\$36.75	4.10
A4259	12.68	8.69	31.47	14.51	-14.43	10.95	13.64	7.40	41.64	12.00	5.36
A4323	8.68	1.02	88.25	1.70	80.41	7.33	15.55	6.25	28.00	7.95	8.41
B4035	10.67	2.40	77.51	4.01	62.42	10.67	9.05	15.18	11.30	-5.90
E0135	83.43	39.36	52.82	65.73	21.22	69.57	16.61	95.60	-14.59	73.42	12.00
E0163	109.74	32.30	70.57	53.94	50.85	89.16	18.75	112.50	-2.52	100.00	8.88
E0178	120.74	N/A	N/A	N/A	N/A	101.87	15.63	118.31	2.01	111.90	7.32
E0180	227.01	94.20	58.50	157.31	30.70	222.17	2.13	287.50	-26.65	210.20	7.40
E0181	251.58	71.00	71.78	118.57	52.87	230.40	8.42	242.05	3.79	231.65	7.92
E0260	1,754.55	762.10	56.56	1,272.71	27.46	1,359.10	22.54	1,608.91	8.30	1,397.65	20.34
E0277	7,933.91	5,297.50	33.23	8,846.83	-11.51	6,341.10	20.08	3,912.50	50.69	7,000.00	11.77
E0570	206.2	32.24	84.37	53.84	73.89	158.51	23.14	182.0	11.74	160.29	22.27
E0730	365.76	165.00	54.89	275.55	24.66	353.45	3.37	645.00	-76.35	334.39	8.58
E0776	142.45	50.25	64.72	83.92	41.09	108.62	23.75	39.10	72.55	116.71	18.07
K0001	570.68	127.72	77.62	213.29	62.63	456.12	20.07	533.50	6.52	530.00	7.13
K0011	5,270.30	2,767.64	47.49	4,621.96	12.30	4,912.16	6.80	5,347.83	-1.47	5,097.40	3.28

Sources: Centers for Medicare & Medicaid Services, Medicare Fee Schedules, January 2002; Department of Veterans Affairs (VA), Pharmacy Benefit Management, Drug & Pharmaceutical Prices, March 25, 2002; VA, National Acquisition Center, Federal Supply Schedule Contracts, March 2002; Office of Inspector General (OIG), Survey of State Medicaid Agencies, March 2002; OIG Survey of Medical Equipment Suppliers, March 2002; OIG Survey of Federal Employee Health Plans (FEHPs), March 2002.

Findings

For some of the items in our analysis, Medicare consistently paid more than the other payers we reviewed. For example, median prices from all four sources (VA, Medicaid agencies, FEHB Plans, and retail suppliers) were more than 10 percent lower than Medicare rates for 3 of the 16 items. These items were powered pressure-reducing air mattress, nebulizer with compressor, and IV pole. Additionally, three of the four sources had prices that were at least 10 percent less than Medicare for another four items. These items were lancets, sterile saline irrigation solution, walker, and semi-electric hospital bed. A more detailed discussion of the price comparisons follows:

Department of Veterans Affairs

Medicare's reimbursement amount was greater than the VA median price for 15 of the 16 items reviewed. We could not find a VA price for the remaining item. The VA median prices ranged from 31 to 88 percent less than the Medicare prices. Maximum potential total savings would be \$958 million per year if Medicare were to adopt these median VA prices. In addition to comparing the Medicare price to the median VA price without a markup, we have compared it to the median VA price with a 67 percent markup. In the August 13, 1999 Federal Register, when CMS compared Medicare prices to median VA prices, they added a 67 percent markup to the VA prices. We used CMS' 67 percent figure since it was the only available data concerning a potential markup percentage. We did not verify or update the CMS markup percentage, nor do we advocate this as the appropriate markup to VA prices. We have presented the 67 percent markup price comparison solely to provide an example of possible savings, which take into account the distinction between Medicare as a payer and the VA as a purchaser of medical equipment and supplies. A mark up of 67 percent would result in potential savings of \$440 million.

Medicaid Prices

The Medicare reimbursement was more than the Medicaid reimbursement for 15 of the 16 items reviewed. Medicare reimbursed the same as Medicaid for the remaining item. Median Medicaid prices ranged from 0-24 percent less than Medicare prices. If Medicare had used the median Medicaid prices for reimbursement on these items, the program could have saved \$193 million.

Federal Employee Health Plan Prices

Medicare reimbursed more than the FEHB Plans median price for all but one of the items reviewed. The FEHB Plans prices ranged from 3 to 22 percent lower for the 15 items with reimbursement rates lower than Medicare. If Medicare were to reimburse based on FEHB Plan median prices, the program could save \$118 million.

Retail Prices

Medicare prices were more than the median retail price for 10 of the 16 items. These median prices ranged from 2 to 73 percent less than the Medicare price for the item. Potential Medicare savings would reach \$84 million if Medicare used median retail prices for reimbursement on these 16 items.

Competitive Bidding Demonstration Prices

I would also like to note that four of the items in our analysis (saline solution, enteral feeding supply kits, semi-electric hospital beds, and standard wheelchairs) have been, or are currently, in Medicare's competitive bidding demonstrations for DME, prosthetics, orthotics, and supplies. Competitive bid prices were 8 to 33 percent less than Medicare reimbursement rates for these four items.

INHERENT REASONABLENESS

CMS has certain authorities to control unreasonably high or low payment levels for medical equipment and supplies. Using the inherent reasonableness process, CMS is permitted to use other payment methodologies to align payment amounts with current market prices. Congress gave CMS added flexibility in making inherent reasonableness adjustments in the Balanced Budget Act of 1997. The law allows CMS to make inherent reasonableness adjustments, without formal rulemaking, as long as the annual adjustments are 15 percent or less. For these adjustments, CMS is required to describe in regulation the factors to be used in determining when payment amounts are not inherently reasonable and those factors to be considered when establishing reasonable payment amounts.

In 1998, CMS published an interim final rule revising the inherent reasonableness regulations. The DMERCs then surveyed retail prices for products they believed might have excessive Medicare payment rates. The DMERCs notified sup-

pliers that they proposed to adjust Medicare payments for eight products and solicited public comments. The medical equipment and supplies industry raised concerns about the proposed reductions, and CMS suspended them.

The CMS also attempted to use the inherent reasonableness process in August 1999 by issuing a proposed notice to replace current fee schedules and implement special payment limits for five items of DME and one prosthetic device. The CMS determined that Medicare reimbursement for the six items was grossly excessive relative to the amount paid by the VA, and therefore not inherently reasonable. The CMS increased the median VA wholesale prices by a mark up of 67 percent to make a valid comparison between Medicare and VA prices.

Because of concerns associated with the inherent reasonableness process, the Congress passed legislation in November 1999 prohibiting CMS from using its inherent reasonableness authority until a GAO report on the subject was issued, and a final rule has been published that responded to the GAO report and to public comments. The GAO report, issued in July 2000, found that there was sufficient evidence to indicate that Medicare overpays for most of the items identified by the DMERCs in 1998, and that the use of the inherent reasonableness process for some items was justified. For other items, GAO questioned the rigor that carriers used in their collection of pricing data. The GAO recommended that CMS define what grossly excessive or deficient prices were in the final rule on the inherent reasonableness process. It also recommended that CMS develop and implement a more structured and consistent data collection sampling and survey methodology for inherent reasonableness reviews. In addition, GAO recommended that CMS monitor patient access to products with reduced payments. To date, the final rule for inherent reasonableness has not been promulgated.

COMPETITIVE BIDDING

The Balanced Budget Act of 1997 authorizes CMS to enter into competitive bidding demonstrations for some categories of DME, prosthetics, orthotics and supplies. Using this authority, CMS has conducted multiple competitive bidding demonstrations with promising results.

In the first demonstration, CMS selected five categories of DME, prosthetics, orthotics and supplies for competitive bidding in Polk County, Florida. Payments under the first demonstration began on October 1, 1999 and were in effect through September 30, 2001. Medicare implemented a second round of competitive bidding in Polk County in October 2001 for four product categories. Payments under this demonstration will remain in effect through September 30, 2002. The CMS estimates savings for Medicare and Polk County beneficiaries of 17 percent (\$1.3 million) annually as compared to payments that would have been incurred under the year 2000 Medicare fee schedules.

Medicare implemented an additional competitive bidding demonstration in San Antonio, Texas from February 1, 2001 through December 31, 2002 for five product categories. The CMS estimates 22 percent savings with this round of competitive bidding.

INVESTIGATIVE CASES

In addition to our audits and evaluations, the OIG has aggressively investigated individuals and entities that have defrauded our programs in this area. Between 1996 and 2001, our investigations led to 88 successful criminal prosecutions of DME suppliers. During this same period, there were 82 civil settlements or judgments imposed. Together, these criminal convictions and civil adjudications resulted in more than \$277 million in restitution, fines and penalties being ordered by the courts. Also, during this time period, 166 exclusions were imposed on DME companies or their owners and employees.

I would like to highlight two of these cases for you today. The first case involved the misbranding of a SureStep glucose meter. The company submitted documents to the Food and Drug Administration (FDA) and marketed the SureStep glucose meter without disclosing two defects that led some users to become medically compromised. In this case, the equipment manufacturer was willing to risk the death of beneficiaries from the use of defective equipment because it could make so much money selling glucose monitoring strips for use with the meter. This company plead guilty to the misbranding allegation and paid a \$30 million criminal fine in addition to a \$30 million civil penalty. The second case involved one of the nation's largest suppliers of respiratory services. Allegations included submission of forged and falsified documents, self-qualifying of oxygen tests, double billing, claims for undelivered items, claims for deceased patients and inflated claims. A random sample of filed from one of the company's subsidiaries revealed a 95 percent error rate. The

company agreed to pay the government \$17 million to resolve its liability under the False Claims Act for these allegations.

CONCLUSION

Mr. Chairman, over the years you have expressed concern that Medicare payments for many medical supplies remain excessive when compared to those of other payers. I know that you have worked diligently to safeguard taxpayer dollars and protect the Medicare program and its beneficiaries from fraud and abuse. We greatly appreciate your efforts. CMS also has made significant improvements over the years to this important benefit including consolidating claims processing, establishing supplier standards and requiring supplier applications. Competitive bidding also has shown promising initial results.

Our work on the 16 items, as well as our prior work, documents that Medicare pays too much for some medical equipment and supplies. We believe that fundamental reform is needed to ensure that Medicare and its beneficiaries pay a fair price. Fortunately, two promising reforms which we have long supported are already available for use. In fact, it is noteworthy that for nine items in our review, CMS has proposed reducing prices through the inherent reasonableness process or has used competitive bidding to actually lower prices. However, CMS needs to complete its inherent reasonableness regulation, and the Administration and the Congress need to work together to expand the competitive bidding provision beyond the demonstration phase.

Thank you for the opportunity to discuss these important issues. I will be happy to answer your questions.

APPENDIX A.—PRICE COMPARISONS FOR 16 MEDICAL EQUIPMENT AND SUPPLY ITEMS METHODOLOGY

For the items reviewed, we calculated the median price from each source (VA, Medicaid agencies, FEHB Plans, and retailers) and compared it to Medicare's median price. We then calculated the percentage difference between the Medicare price and the median prices of each of the four sources (i.e., we found the difference between the Medicare price and the other source's lower price, and divided the difference by the Medicare price). For those items where the Medicare price was higher than the source's price, we multiplied this percentage by the total Medicare payments for the item in 2000 to get an estimated annual dollar savings. We used the January 2002 Medicare fee schedules to determine the Medicare purchase prices for the 16 Medicare codes in our sample. Since fee schedule rates for the same codes differ among States, we calculated the median rate from the fee schedule rates for all 50 States, Puerto Rico, and the Virgin Islands.

For the seven codes in the capped rental payment category, we used the Medicare formula to calculate how much these items would cost if beneficiaries chose to own them. For all but one of the items, the least expensive purchase price is equal to 13 months of rental, and for the remaining item (motorized wheelchair) it is equal to 10 months of rental. Six codes in our sample are items that may be purchased new or used. In these cases, we used the fee schedule purchase price for new items. The remaining three codes in our sample are supplies that cannot be re-used and there is only one possible purchase price for these items in the fee schedule.

We also gathered information from past and current CMS competitive bidding demonstration projects in Polk County, Florida and San Antonio, Texas. We reviewed the list of items included in the demonstrations to determine if any of the 16 items we reviewed had competitive bid prices.

We sent a request to the VA's National Acquisition Center to provide us with current Federal Supply Schedule prices for equipment and supplies that matched the description of our 16 Medicare codes. The National Acquisition Center handles the largest combined contracting activity within the VA. The National Acquisition Center determined which vendor contracts might contain products that matched the descriptions for 14 of the codes, and sent us the contract containing prices. For the two remaining codes (A4253—blood glucose test strips and A4259—lancets), we obtained Federal Supply Schedule prices from the VA's Pharmacy Benefit Management website. From the available VA data, we identified items that we believed matched the descriptions of our Medicare codes.

We sent requests to 52 State Medicaid agencies and 58 fee-for-service FEHB Plans to provide current reimbursement prices for items matching the description of the 16 Medicare codes. We received responses from 40 Medicaid agencies and 30 FEHB Plans. Not all of the respondents could provide rates for every item.

Finally, for each of the 16 codes, we identified Medicare suppliers that received the highest payments for that particular code in 2000. For each code we obtained

retail prices from 10 suppliers. We asked suppliers how much it would cost to buy the item, in cash, including tax and delivery charges. For three of the 16 items—blood glucose test strips for home blood glucose monitors, lancets, and enteral feeding supply kits for use with pumps—we requested more than one price. Generally, blood glucose test strips are made to fit specific brands of equipment. Therefore, prior to calling suppliers, we identified two commonly-used brands of test strips. We then requested the prices of these two brands of test strips from suppliers. Blood glucose test strips and lancets are often sold through mail order which may result in different prices than retail prices. Therefore, we asked for the mail order as well as the retail price. For enteral feeding supply kits, we identified two supply kits billed under code B4035, and then we asked suppliers for the prices of both supply kits. In addition, the enteral feeding supply kits are covered by Medicare on a per day basis, while the prices we were quoted were per unit. In our analysis, we compared the per-unit price to Medicare's per-day price.

Senator HARKIN. Ms. Rehnquist, thank you very much. I did not know that timing clock was on. I wanted to give you plenty of time, but we will get into a discussion.

Again, let me just thank you and your whole office for really being diligent on this and doing it in a good time frame and not dragging it out for a long time.

Ms. REHNQUIST. Well, thank you.

Senator HARKIN. We really appreciate that very much. I went over the whole report. I just thought you did everything exemplary in terms of the investigation and bringing to light what we were paying on these items. So, again, I thank you and, through you, the staff that works for you.

Ms. REHNQUIST. They deserve a lot of the credit.

Senator HARKIN. Thank you.

**STATEMENT OF LESLIE G. ARONOVITZ, DIRECTOR, HEALTH CARE,
PROGRAM ADMINISTRATION AND INTEGRITY ISSUES, UNITED
STATES GENERAL ACCOUNTING OFFICE**

Senator HARKIN. Now we will turn to Ms. Aronovitz. Leslie Aronovitz is a Director of the Health Care Team for the GAO, the General Accounting Office. She received her bachelor's degree from the University of Georgia and her M.B.A. from the Boston University. Again, Ms. Aronovitz, your testimony will be made a part of the record in its entirety, but please proceed as you desire.

Ms. ARONOVITZ. Thank you, Mr. Chairman. I am pleased to be here today to discuss Medicare payment methods for medical equipment, supplies, and covered outpatient drugs.

You have heard from the Inspector General about the wide disparities between Medicare's payment rates and the prices paid by others such as the VA or even retail customers. In a similar vein, we reported last year on Medicare's policy of paying list price for covered outpatient drugs, while physicians and pharmacy suppliers could purchase them at substantial discounts—in one case as high as 86 percent off the list price.

To best understand how to begin fixing this problem, I would like to take a minute to review the context in which Medicare operates as a payer of health care services and products. This will help explain in part why effective solutions have been so elusive.

**MEDICARE PAYMENT APPROACHES LACK FLEXIBILITY TO KEEP PACE
WITH MARKET CHANGES**

Medicare is a highly visible public program with certain obligations that may not be consistent with efficient business practices.